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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,376	10/18/2001	Richard James Lewis	14455	8463

7590 03/11/2004

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/806,376	LEWIS ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *8-12,14-18 and 21-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,13,19 and 20* is/are rejected.

7)☒ Claim(s) *1,7 and 19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. PCT/AU99/00843.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1-15-02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-23 are pending.

Applicants' amendment (filed 2 February 2004) to claims 8, 14, and 21-22 has been entered.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1-7, 13 and 19-20 (see the response filed 2 February 2004) is acknowledged. The traversal is on the ground(s) that the current application is a 371 of PTC/AU99/00843 and the application claims are all linked in a single general inventive concept; thus, Groups I-V are related as a single invention (see page 7). The applicants' argument has been fully considered but it is not persuasive because while no prior art in record teaches or suggestes the claimed ρ-conotoxin peptide, the polynucleotide (Group III) encoding said peptide is structurally distinct from the peptide (Group I). Thus, the compositions of Groups I and III thus do not constitute a common technical feature linking all claims, as defined by PCT Rule 13.2 and 37 CFR 1.475(a); a holding of lack of unity is therefore proper. In addition, the biopolymers of Groups I and III would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use, as well as are required separate search. Thus, the restriction requirement is still deemed proper and is therefore made FINAL.

The claims will be examined insofar as to the elected patentably distinct peptide of Group I, SEQ ID NO:1. Claims 8-12, 14-18 and 21-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, elected claims

1-7, 13 and 19-20 together with the elected peptide of SEQ ID NO:1 are under examination to the extent that they are drawn to the elected invention.

Foreign priority

Acknowledgment is made of applicant's claim for foreign priority based on an application Australia PP6273/98 filed 2 October 1998 (see page 1 of Declaration). It is noted, however, that applicant has not filed a certified copy of the Australia PP6273/98 as required by 35 U.S.C. 119(b). The following Office Action is therefore applicable to the pending claims 1-7, 13 and 19-20 not based on the foreign priority date claimed by applicants in the instant application.

IDS

The references listed in IDS filed 15 January 2002 have been considered.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

(1) In page 1, line 18, "Ach" and line 24, "NMDA" should be spelled out in full for the first instance of use. See also page 2, line 21 "ρ-TIA"

(2) In page 2, line 4, "α-Adrenoceptor" should be change to "α-adrenoceptor".

(3) In page 2, line 26, "SEQ ID NO.1" should be changed to "(SEQ ID NO:1)"; and page 3, line 11, "SEQ ID NO.2" should be changed to "(SEQ ID NO:2)".

(4) In page 4, line 16, "sidechain" should be changed to "side chain".

(5) In page 28, line 29, "ρ-TIA – FNWRCCLIPACRRNHKKFC SEQ ID NO.1" should be changed to ""ρ-TIA FNWRCCLIPACRRNHKKFC (SEQ ID NO:1)"; line 31, "SEQ ID NO.3" should be changed to "SEQ ID NO:3". See also page 29, line 23, "SEQ ID NO. 5".

(6) In claim 1, "the sequence: FNWRCCLIPACRRNHKKFC SEQ ID NO.1" should

be changed to "the sequence of SEQ ID NO:1 (FNWRCCLIPACRRNHKKFC)".

(7) In claim 7, "residues respectively" should be changed to "residue, respectively".

(8) In claim 19, "isolate" should be changed to "isolated".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7, 13 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites "α1-adrenoceptor"; the recitation is unclear as to whether or not it refers to epinephrine, norepinephrine or isoproterenol, or a dopamine receptor. See also claim 19. The dependent claims are also rejected.

Claim 2 is indefinite in the recitation "**or** such a sequence" because it is unclear as to which sequence the recitation refers; is the sequence SEQ ID NO:1, or any conotoxin? Further, claim 2 is awkward in "one or more amino acid deletions, additions, substitutions or side chain modifications" because one (a single) amino acid alteration cannot result in *multiple* deletions, or/and addition or/and substitutions or/and side chain modifications.

Claim 4 recites "Ach receptor" which should be fully spelled out, or the recitation is indefinite. Also, claim 4 is unclear in the recitation "having no or negligible activity"; to which standard the said activity is compared thus negligible?

Claim 5 recites "α_1–subtype"; the recitation is indefinite since it is an incomplete recitation; does the recitation refers to an α_1–subtype of adrenergic receptor or <u>any receptor</u> α_1–subtype (e.g., GABAA receptor subtypes: α_1, α_2, and α_3) or <u>any signing protein</u> α_1–subtype (e.g., G-protein alpha subunit subtypes: α_{i1}, α_{i2}, and α_{i3})?

Claim 13 recites "the resultant ρ-conotoxin peptide"; this recitation lacks antecedent basis in the claim and claim 1 from which claim 13 depends, and claim 13 is unclear regarding from what the peptide is resulted. In addition, claim 13 is indefinite in "an activity *associated with* said other peptide or protein" because the phrase "associated with" is not equal to "<u>of</u>" that indicates that the said peptide or protein fully possesses said activity. Is said activity contributed by (i) the <u>entire</u> chimeric protein that comprises the ρ-conotoxin peptide <u>and</u> heterologous peptide or protein, or (ii) <u>only</u> said other peptide or protein ? Additionally, claim 13 is indefinite in "segment or sequence"; does the sequence refer to full-length <u>or</u> a fragment (segment) of the recited "another biologically active peptide or protein"?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 13 and 19-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification does not describe ρ-conotoxin variant which is resulted from mutation (deletion, additions ,substitution or side chain modifications having activity other than conotoxic activity. Therefore, these structural variations lack written description. This rejection can be overcome by placing functional language into the claims that structure and function are correlated.

Note that claim 13 recitation "chimeric peptide" and claim 19 recitation recombinant ρ-conotoxin" are also encompassed in the above-mentioned structural variants. Thus, the claims are also included in this rejection.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

March 8, 2004

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER